UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated, Plaintiff, v. SHIRE LLC, SHIRE U.S., INC., ACTAVIS ELIZABETH LLC, AND ACTAVIS LLC, Defendants.	Case Action No. _____ **CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff"), brings this class action on behalf of itself and all others similarly situated against defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire"), and Actavis Elizabeth LLC and Actavis LLC (collectively, "Actavis")[1] and alleges as follows based on: (a) personal knowledge; (b) the investigation of their counsel; and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiff on behalf of a class of direct purchasers of the extended release formulation of guanfacine hydrochloride ("guanfacine"), sold by Shire under the brand name Intuniv. Intuniv is a prescription drug indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents. Plaintiff seeks overcharge damages arising out of Shire's unlawful agreement with Actavis not to compete in the market for extended-release guanfacine.

[1] Shire and Actavis are collectively referred to as "Defendants."

2. On April 25, 2013, Shire entered into an unlawful non-competition agreement with Actavis. Under the agreement (the "Reverse Payment Agreement" or "Agreement"), Actavis agreed to delay marketing its less-expensive generic version of Intuniv for over a year and a half, until December 1, 2014. In exchange, Shire agreed to pay Actavis — and did, in fact, pay Actavis — by forbearing from launching an authorized generic to compete with Actavis's generic Intuniv during its 180-day exclusivity period, effectuating a payment of tens of millions of dollars from Shire to Actavis. In compliance with the Agreement, even though Actavis was granted final approval by the U.S. Food and Drug Administration ("FDA") to launch its less-expensive generic Intuniv on October 5, 2012, Actavis did not come to market until December 1, 2014.

3. But for Defendants' unlawful Reverse Payment Agreement, one or more generic versions of Intuniv would have entered the market in or around May of 2013. Thus, absent Defendants' unlawful Reverse Payment Agreement, Plaintiff and the members of the class would have been able to satisfy their extended-release guanfacine requirements at significantly lower prices substantially earlier than they did, rather than being forced to pay for brand and generic Intuniv at higher prices because of the unlawful agreement.

4. Defendants' unlawful Reverse Payment Agreement was designed to and did in fact: (i) delay and/or preclude the entry of less-expensive generic versions of Intuniv; (ii) delay the introduction of an authorized generic version of Intuniv, which otherwise would have appeared on the market at a significantly earlier time and lowered prices further; (iii) fix, raise, maintain or stabilize the prices of extended-release guanfacine; (iv) permit Shire to maintain a monopoly for extended-release guanfacine; (v) allocate 100% of the extended-release guanfacine market in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Shire for up to 19 months; and (vi) allocate

100% of generic Intuniv sales in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Actavis for 6 months.

5. Defendants thus violated §§ 1 and 2 of the Sherman Act through their anticompetitive Reverse Payment Agreement, which unreasonably restrained competition in the market for extended-release guanfacine and improperly maintained and extended Shire's market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of Intuniv.

II. JURISDICTION AND VENUE

6. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the class (defined below) resulting from Defendants' unlawful restraint of trade and maintenance of market and monopoly power in the market for extended-release guanfacine in the United States, including its territories, possessions and the Commonwealth of Puerto Rico. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

7. Defendants transact business within this district, and they carry out interstate trade and commerce in substantial part in this district and/or have an agent and/or can be found in this district. Defendant Shire U.S., Inc. has a principal place of business in this district. Venue is therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

III. PARTIES

A. Plaintiff

8. RDC is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at

50 Jet View Drive, Rochester, New York 14624. During the Class period, RDC purchased branded Intuniv directly from Shire, and purchased generic Intuniv directly from Actavis, and was injured as a result of Defendants' unlawful conduct.

B. Defendants

9. Shire U.S., Inc. maintains its principal place of business and U.S. Operational Headquarters at 300 Shire Way, Lexington, Massachusetts 02421. Throughout the Class Period, Shire U.S., Inc. marketed and sold Intuniv. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Intuniv.

10. Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Upon information and belief, Shire LLC is a party to the anticompetitive reverse payment agreement at issue herein. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including Intuniv. Throughout the Class Period, Shire LLC marketed and sold Intuniv.

11. Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Upon information and belief, Actavis LLC is party to the anticompetitive reverse payment agreement at issue herein, and the successor in interest to Actavis Inc. Actavis LLC develops, manufactures, markets, and sells generic pharmaceutical products in the United States.

12. Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in New Jersey. Upon information and belief, Actavis Elizabeth LLC is party to the anticompetitive reverse payment agreement at issue herein. Actavis Elizabeth LLC develops, manufactures, markets, and sells generic pharmaceutical products in the United States.

13. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized,

ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

14. With respect to all of the conduct complained of herein, at all relevant times Shire acted in concert with Actavis.

IV. CLASS ACTION ALLEGATIONS

15. Plaintiff brings this action on behalf of itself and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as a representative of a Class defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased brand or generic Intuniv directly from any of the Defendants at any time during the period from May 1, 2013 through the date on which the anticompetitive effects of Defendants' challenged conduct ceased (the "Class").

16. Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

17. Joinder of the members of the Class is impracticable. Plaintiff believes the Class members are numerous and widely dispersed throughout the United States and its territories, possessions and the Commonwealth of Puerto Rico. Further, the Class is readily identifiable from information and records in the possession of Defendants. Direct notice to the members of the Class can be made upon obtaining the relevant information and records in the possession of Defendants.

18. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful

conduct by Defendants, *i.e.*, they paid artificially inflated prices for extended-release guanfacine and were deprived of the benefits of competition from less-expensive generic versions of Intuniv as a result of Defendants' wrongful conduct.

19. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

20. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

21. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

22. Questions of law and fact common to the Class include:

a. Whether the pay-for-delay conduct alleged herein constitutes a violation of the antitrust laws;

b. whether Defendants conspired to suppress generic competition to Intuniv;

c. whether, pursuant to the Agreement, Actavis agreed to, and did, delay its entry into the market with generic Intuniv;

d. whether, pursuant to the Agreement, Shire agreed to, and did, delay its entry into the market with authorized generic Intuniv;

e. whether, pursuant to the Agreement, Shire made a payment to Actavis, and the amount of such payment;

f. whether the payment Shire made to Actavis was for a purpose other than delaying Actavis's entry into the market for extended-release guanfacine;

g. whether there are legitimate procompetitive justifications explaining Shire's payment to Actavis, namely being merely for avoided litigation costs or for services Actavis was to perform for Shire;

h. whether Defendants' Agreement suppressed generic competition to Intuniv;

i. whether Defendants' Agreement created a bottleneck to further delay generic competition for extended-release guanfacine;

j. whether Defendants' Agreement harmed competition in the extended-release guanfacine tablet market;

k. whether Defendants conspired or attempted to maintain Shire's market and/or monopoly power in the extended-release guanfacine market;

l. whether Shire possessed market and/or monopoly power in the market for extended-release guanfacine;

m. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

n. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

o. whether, and to what extent, Defendants' challenged conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class in the nature of overcharges; and

p. the quantum of overcharges paid by the Class in the aggregate.

23. Class action treatment is a superior method for the fair and efficient adjudication of the controversy because, in addition to other benefits, such treatment will permit a large number of similarly situated persons to prosecute their claims in a single forum simultaneously, efficiently, and without the

unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining overcharge damages for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

24. Plaintiff knows of no difficulty to be encountered in the maintenance of this action as a class action that would preclude its maintenance as a class action.

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

25. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer who creates a new drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

26. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that claims either the approved drug or approved methods of use of the drug and could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand drug prior to the expiration of the listed patent(s). Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

27. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the

resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

28. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug — that is, that the generic drug is both pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq.*

29. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug is absorbed at the site of drug action to the same extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in dosage form, safety, strength, route of administration, and intended use.

30. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, allowing their substitution for the brand when a prescription for the brand is presented at the pharmacy.

31. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' financial incentives to create new and innovative products.

32. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic revenues for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[2]

2. Paragraph IV Certifications

33. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book as claimed by the brand drug. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

[2] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at* https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf (last accessed January 8, 2017).

a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand drug has expired (a "Paragraph II certification");

c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

34. If a generic manufacturer files a Paragraph IV certification that the listed patent is invalid or will not be infringed, it must give notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification confers standing to sue for patent infringement regardless of the merits of such an action. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot grant final approval to authorize the generic manufacturer to go to market with its product. Accordingly, the timely filing of an infringement action provides the patent owner with the equivalent of an automatic preliminary injunction preventing final FDA approval of the challenged ANDA for up to 30 months, even if there is no merit to the infringement action.

35. As an incentive to spur generic companies to seek approval of generic alternatives to brand drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. The first generic applicant often receives 180 days of market exclusivity, meaning that the FDA will not approve any other ANDA for that same generic drug for at least six months. This allows the first filer to be free from competition from other generic companies for six months. However, the brand company is free to (and often does) launch its own "authorized generic" during the 180-day exclusivity period.

36. A first-filer's generic exclusivity period can sometimes assist the brand manufacturer in delaying generic launches from other manufacturers. If a first-filer agrees with the brand manufacturer to delay launching its generic drug, it also delays the start of the 180-day exclusivity period. This practice is known as "exclusivity parking." This strategy creates a bottleneck in the market because later generic applicants are prevented from launching their generic versions until the first-filer's 180-day exclusivity period elapses.

B. Generic Versions of Brand Drugs are Significantly Less Expensive than Their Corresponding Brand Versions.

37. Typically, AB-rated generics are priced significantly below their brand counterparts. "Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.'"[3]

[3] *See What Are Generic Drugs?*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm (last accessed January 8, 2017).

1. Generic Versions of Brand Drugs Quickly and Predictably Take Sales from Their Corresponding Brand Versions

38. In every state, pharmacists are permitted (and in some states, required) to substitute a generically-equivalent product for the brand product prescribed, unless the doctor has indicated that the prescription for the brand product must be "dispensed as written." Because of the significant savings they allow and other institutional features of the pharmaceutical industry, generic versions are substituted by pharmacists who are presented with a prescription for the brand counterpart immediately upon launch of the generic.

39. As more generic sellers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic sellers. Pharmacy substitution, and thus the loss of sales volume by the brand drug to the corresponding generic, thereby accelerates. According to a recent FTC staff study, within one year of generic entry, 90% of prescriptions are filled with the brand's generic substitute, and at prices that "are, on average, 85% lower than the pre-entry branded drug price." *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FTC Staff, January 2010 at 8.

40. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; or (b) purchase the brand drug at a reduced price.

41. Until a generic manufacturer enters the market, there is no generic drug to substitute for and otherwise compete with the brand drug, thereby allowing the brand manufacturer to continue to charge supracompetitive prices profitably, without losing a substantial portion of its brand sales. Consequently, brand manufacturers have a strong incentive to delay the introduction of generic competition into the market, including paying generic companies to delay launching their generic products, such as in this case.

2. No-Authorized-Generic Promises Are a Means By Which Brand Companies Pay Generic Companies to Delay Generic Competition

42. One mechanism employed by brand companies to thwart generic competition is to make a payment to a first-filing generic company in the form of the brand company's promise not to launch an "authorized generic" version of the brand drug during the first 180 days of generic marketing. An authorized generic is the brand drug, manufactured just like the brand product, but sold as a generic product under the same approval as the brand product's original NDA. Because the brand manufacturer already has approval to sell its brand drug, it does not need to file an ANDA, or obtain any additional approval, to market an identical generic version of its own brand drug.

43. ANDA filers have no patents on, and no right to be free from, an authorized generic version of the brand drug.

44. For the brand company, an authorized generic launched during the first 180 days of generic marketing provides a low cost, low risk means to regain some of the revenue lost from the termination of brand exclusivity. For the generic manufacturer enjoying exclusivity as the first generic to be marketed, however, an authorized generic launch has a huge negative impact on revenue. A generic company generally earns about 80% of its total income from a given generic product during the period that it is the sole generic on the market. An authorized generic, when launched during that time, is typically priced competitively as against the other generics and typically leads to lower generic prices, and will capture 50% or more of total generic sales during that period.

45. A brand's promise not to launch an authorized generic during the initial period of generic marketing is thus a very valuable payment to the generic company that is the first-filer generic entrant. It doubles the first-filer generic entrant's sales volume during that time, and, because it removes a source of price

competition from the market, it more than doubles the first-filer generic entrant's revenues and profits. Correspondingly, a brand's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits that the authorized generic would otherwise have created for the brand. Those revenues and profits are instead ceded, by way of the no-authorized-generic promise, to the generic company.

46. In a report by the Federal Trade Commission ("FTC") issued at the request of Congress in August 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ("*Authorized Generic Drugs*"), the FTC concluded that no-authorized-generic promises are being used as a payment by brands to generics for delayed generic entry. The FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition reduces the first-filer generic's revenues by more than 50% during the first 180 days of generic marketing.[4]

47. The FTC found that a generic company makes significantly less money when it competes with an authorized generic because (1) the authorized generic takes a significant share of generic sales away from the first-filer (around 50%), and (2) wholesale and retail prices decrease when the first-filer faces an authorized generic due to competition between the two. Both of these factors reduce the generic company's sales and revenues. With a no-authorized-generic promise, the generic company avoids this reduction in revenue. The FTC noted that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic

[4] *Authorized Generic Drugs* at iii, vi, 41-48, 57-59, *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed Jan. 8, 2017).

competitors for delaying entry. These agreements can be part of 'pay-for-delay' patent settlements, which have long concerned the Commission." *See id.* at vi.

48. A 2006 study sponsored by the brand drug company trade association, PhRMA, similarly found that competition from an authorized generic results in lower generic prices.

49. An agreement between a brand and generic drug company — horizontal competitors — that the brand company will withhold an authorized generic from the market in exchange for the generic company's agreement to delay market entry with its generic version of the brand drug, injures consumers twice over: first, by prolonging the period during which only the high-priced brand is available, and second, by ensuring that, once delayed generic competition begins, generic prices are artificially inflated because of the absence of the authorized generic.

50. For a first-filer generic like Actavis, of a brand product like Intuniv, the difference between (1) selling the only generic product and (2) selling a generic product while competing against an authorized generic, for the first six months of generic marketing, constitutes a very large payment — reaching tens of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic and, by necessary implication, its absence.

51. No-authorized-generic promises, like the one Shire made as payment in exchange for Actavis's promise to delay introduction of generic Intuniv, thus allow horizontal competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

VI. FACTUAL ALLEGATIONS

A. Background

1. Approval of Brand Intuniv and its Purported Patent Protection

52. Intuniv is a prescription extended release tablet approved to treat attention-deficit/hyperactivity disorder (ADHD). The active ingredient in Intuniv, guanfacine hydrochloride ("guanfacine"), is not new. It was first marketed in 1986 under the brand name Tenex as a treatment for hypertension. By the time Intuniv was approved by the FDA in September 2009 for the treatment of ADHD, the active ingredient formulation of guanfacine had been off patent and in the public domain for years.

53. While other drugs are available to treat the same or similar medical conditions, they are not AB-rated to Intuniv, cannot be automatically substituted for Intuniv by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Intuniv, and are not economic substitutes for, nor reasonably interchangeable with, Intuniv.

54. On September 2, 2009, the FDA approved NDA 022037, submitted by Shire Pharmaceuticals, Inc., which sought to market extended-release guanfacine tablets in 1 mg, 2 mg, 3 mg, and 4 mg dosages under the brand name Intuniv. Upon FDA approval, Shire received a three-year Hatch-Waxman regulatory exclusivity period that was set to expire on September 2, 2012.

55. Shire listed several patents in the Orange Book as covering Intuniv, specifically, U.S. Patent Nos. 5,854,290 (the '290 patent), 6,287,599 (the '599 patent), and 6,811,794 (the '794 patent).

56. The '290 patent is a method of use patent, entitled "Use of guanfacine in the treatment of behavioral disorders." It was issued on December 29, 1998 and was dedicated to the public by Shire in March 2012. Method of use patents can be easier to overturn than patents pertaining to the composition of

matter of an active ingredient. A court found the '290 patent to be invalid on July 23, 2012.

57. The '599 patent, entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles," purportedly covers Intuniv's coating which allows for the extended release of the active ingredients. It was issued on September 11, 2001 and is set to expire on December 20, 2020.

58. The '794 patent also purportedly covers Intuniv's extended release coating, and is likewise entitled "Sustained release pharmaceutical dosage forms with minimized pH dependent dissolution profiles." The patent was issued on November 2, 2004 and is set to expire on July 4, 2022.

2. Actavis's ANDA Threatened Shire's Weak Patents

59. The pharmacokinetic profile of Intuniv was easily replicable. On December 29, 2009 — less than four months after Shire received FDA approval — Actavis submitted an ANDA to the FDA, seeking to market a generic version of Intuniv.

60. Actavis's ANDA included a Paragraph IV certification stating that the commercial manufacture, use and/or sale of its generic Intuniv product would not infringe any claims of the three patents purportedly covering Intuniv, and/or that those patents were invalid and/or unenforceable.

61. Actavis was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to Intuniv, entitling it to a six-month (180-day) exclusivity period, free from competition from any other ANDA-filing generic company. (This exclusivity, however, would not have protected Actavis from competition from an authorized generic version of Intuniv.) On April 2, 2010, Actavis sent a notification letter to Shire regarding its Paragraph IV certification.

62. Other manufacturers also filed ANDAs seeking to market generic versions of Intuniv subsequent to Actavis's ANDA filing. On January 25, 2010, Teva Pharmaceuticals USA, Inc. filed an ANDA. On January 28, 2010, Anchen Pharmaceuticals, Inc. filed an ANDA (which it later transferred to TWi Pharmaceuticals, Inc.). Mylan Pharmaceuticals, Inc. filed an ANDA on November 30, 2010. Sandoz , Inc. filed an ANDA on December 28, 2010. Teva sent Shire a Paragraph IV notice on March 12, 2010, while Anchen sent its notice on April 23, 2010.

3. Shire Sues to Protect Its Franchise

63. Shire filed lawsuits in the District of Delaware and elsewhere against the would-be generic manufacturers, alleging infringement of the patents purportedly covering Intuniv. Shire sued Teva on April 22, 2010 (*Shire LLC, et al. v. Teva Pharmaceuticals USA Inc., et al.*, Docket No. 1:10-cv-00329 (D. Del.)), followed by Actavis on May 12, 2010 (*Shire LLC, et al. v. Actavis Elizabeth LLC, et al.*, Docket No. 1:10-cv-00397 (D. Del.)), and Anchen on June 2, 2010 (*Shire LLC, et al. v. Anchen Pharmaceuticals Inc., et al.*, Docket No. 1:10-cv-00484 (D. Del.)). On August 2, 2010, all three lawsuits were consolidated under the Teva docket (1:10-cv-00329).

64. As a result of the above lawsuits, Hatch-Waxman 30-month stays were triggered. Accordingly, the FDA was precluded from approving Actavis's ANDA until (i) the stay expired on October 2, 2012, or (ii) entry of a final judgment that the Intuniv patents were invalid, unenforceable, and/or not infringed. The FDA was also precluded from approving other generic Intuniv ANDAs due to 30-month stays, including Anchen's, Teva's, Mylan's and Sandoz's.

65. Shire understood that its Intuniv patents were weak and subject to invalidation, yet Shire nonetheless asserted its patents against Actavis and the other generic manufacturers.

66. Recognizing that the ’290 patent was exceptionally weak, on March 22, 2012, Shire dedicated the ’290 patent to the public — just days before it would have to submit expert reports on the ’290 patent in the consolidated litigation. The district court later found the ’290 patent invalid by order entered July 23, 2012.

67. The ’599 and ’794 patents were also weak and likely to be found invalid or not infringed by the district court in the consolidated litigation. On March 22, 2012, the district court entered a claim construction order (also known as a *Markman* ruling) that construed claim terms of the ’599 and ’794 patents favorably for the generic defendants. Shire moved for reconsideration of the *Markman* ruling, but its motion was summarily denied by order dated June 20, 2012.

68. On the same day Shire’s motion for reconsideration of the *Markman* order was denied, Anchen moved for summary judgment, stating “the Court’s claim construction order legally precludes [Shire’s] primary argument against Anchen[.]”

69. Investment bank analysts that followed the patent litigation began to recognize the grim situation Shire was facing, and anticipated that Shire would lose the patent fight and that generics would enter the market immediately after the litigation ended. For example, in June 2012 BNP Paribas wrote “[w]e now adopt a bear scenario with Shire losing the litigation vs generic makers (17 Sept 2012) on the two remaining formulation patents (’599/’794) and the entry of generics in mid-2013 after a 6-9 month trial.”

4. Shire Settles with Anchen/TWi

70. While Anchen/TWi’s summary judgment motion was under submission, Shire was susceptible to an adverse ruling at any time. Recognizing that it was likely to lose the patent fight, Shire settled with Anchen/TWi on September 4, 2012, and issued a press release on September 6, 2012. Among the

settlement terms was that Anchen would distribute Shire's authorized generic product.

5. Shire Enters Into an Anticompetitive Settlement Agreement with Actavis

71. From September 17-20, 2012, a bench trial was held on Shire's claims against Actavis and Teva for infringement of the '599 and '794 patents. During the trial, Actavis and Teva presented a number of defenses including that the patents were invalid and/or not infringed.

72. On October 5, 2012, Actavis received final FDA approval on its ANDA, just three days after its 30-month stay expired.

73. Actavis's CEO Paul Bisaro stated in early 2013 that time was "of the essence" for a settlement with Shire, indicating the belief that a favorable decision in the district court was imminent. Actavis knew that if it agreed to settle before such a decision, it could extract advantageous terms from Shire.

74. Shire settled with Actavis on April 25, 2013, before the Delaware District Court issued a ruling on the validity of Shire's patents. Under the settlement agreement, Shire agreed not to launch an authorized generic to compete with Actavis during its 180-day exclusivity period (a "no-AG promise"). In exchange for this promise, Actavis agreed to delay its launch of generic Intuniv until December 1, 2014. The settlement agreement contained a term whereby Actavis agreed to remit to Shire a 25% portion of Actavis's gross profits during the 180-day exclusivity period. These promises composed the Reverse Payment Agreement.

75. Absent the no-AG promise, Shire would have launched an authorized generic simultaneously with Anchen's launch, during Actavis's 180-day exclusivity period, stealing approximately 50% of Actavis's generic sales and substantially lowering the price that drug purchasers paid for generic Intuniv.

Absent the no-AG promise, Actavis would not have agreed to delay its launch until December 1, 2014, and instead would have entered the market, at risk, in or around May of 2013.

76. By paying Actavis to delay its launch using the no-AG promise in this way, Shire was able to continue to reap monopoly profits on branded Intuniv until December 1, 2014. In addition, the no-AG promise allowed Actavis to garner higher prices and double its sales during its 180-day exclusivity period, after its delayed launch.

77. Actavis's agreement to delay launching its generic Intuniv in return for Shire's no-AG promise did not just delay Actavis's own entry into the market. It also created a bottleneck that blocked the output of all other would-be generic Intuniv competitors, because it postponed the inception, and thus the elapsing, of Actavis's 180-day first-filer exclusivity period. Once Actavis's 180-day exclusivity period expired, Teva and Mylan launched their generic Intuniv products on June 2, 2015. Anchen/TWi launched its generic on June 3, 2015, followed by Sandoz on June 4, 2015. These competitors' products would have been on the market far earlier absent the Reverse Payment Agreement, and purchasers would have paid commodity prices for generic Intuniv sooner.

6. The No-AG Promise Was A Very Large Reverse Payment

78. Shire sacrificed substantial revenues and profits by its no-AG promise. Absent the no-AG promise, it would have made economic sense for Shire to launch an authorized generic simultaneously with Actavis's launch so that Shire could retain sales that Actavis's less expensive generic otherwise would capture, rather than ceding those sales to Actavis. As alleged above, an authorized generic product typically captures approximately 50% of the generic sales during the first 180 days of generic marketing and also drives down prices.

79. The no-AG promise was a very large payment to Actavis. Using a conservative approach valued as of the time the Reverse Payment Agreement was entered into, Plaintiff estimates that the no-AG promise constituted a payment of $58.1 million or more from Shire to Actavis.

80. This figure is derived by estimating the difference between (a) Actavis's higher revenues during the 180-day exclusivity period free from competition from Shire's authorized generic (*i.e.*, with the no-AG promise) and (b) Actavis's lower revenues during the same period while facing competition from Shire's authorized generic (*i.e.*, without the no-AG promise). Both of these amounts can be estimated using the well-known dynamics of the pharmaceutical industry and publicly-available information.

81. The higher amount of revenue Actavis would expect to earn from sales of generic Intuniv during the first 180 days of marketing free from competition from Shire's authorized generic (*i.e.*, with the no-AG promise) can be estimated as follows:

a. At the time Defendants entered the Agreement, Shire's annual revenue from sales of Intuniv was approximately $350 million. Thus, at the time of the Agreement, 6 months (180 days) of branded Intuniv sales would generate revenue to Shire of at least $175 million (6/12 * $350,000,000).

b. In the pharmaceutical industry, the first generic is typically expected to take 80% (or more) of the brand's unit sales within six months. Thus, approximately $140 million worth of brand unit sales would be converted to Actavis's generic during the first 6 months Actavis's generic Intuniv was on the market ($175,000,000 * .8).

c. As is also common, with only one generic on the market, the generic is typically priced at 90% of the brand's pre-generic price, which

would result in generic sales revenues during the first 6 months Actavis was on the market of approximately $126 million ($140,000,000 * .9). Thus, the sales revenues Actavis would have obtained during the 6 months that the no-AG promise was in effect were approximately $126 million.

d. Under the Agreement, Actavis agreed to pay Shire a royalty of 25% on Actavis's gross profits on sales of generic versions of Intuniv during the 6 month period that the no-AG promise was in effect. Conservatively applying the royalty on $126 million in sales (as opposed to the lower number that would reflect Actavis's gross profits), and further assuming that royalties were actually paid, this would amount to approximately $31.5 million ($126,000,000 * .25). As a result, even when the amount of the royalty is netted out, Actavis's anticipated revenue during 6 months free from competition from Shire's authorized generic would be, conservatively, $94.5 million ($126,000,000 - $31,500,000).

82. Actavis's substantially smaller revenues, that it would have earned during the first 6 months after its launch if Shire had not promised to refrain from launching an authorized generic for 6 months following Actavis's launch, can be estimated as follows:

a. According to an FDA study of the dynamics of generic competition, the addition of a second generic (such as Shire's authorized generic) drives the average generic price down to 52% of the brand price.[5] Thus, while the generics would still take 80% of brand sales during those first 6 months, or $140 million at the branded Intuniv price, the dollar value of those generic sales would drop to $72.8 million in the presence of an authorized generic (140,000,000 * .52).

[5] *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last accessed January 8, 2017).

b. Actavis would not get 100% of those revenues, however. That is because the unit sales of the generic during those first 6 months would be split evenly between Actavis's generic Intuniv and Shire's authorized generic Intuniv.

c. Thus, without Shire's no-authorized-generic promise, Actavis's revenues from sales of generic Intuniv during the first 6 months of generic marketing would have been approximately $36.4 million (72,800,000 * .5).

83. The incremental revenue that Shire paid to Actavis by the no-AG promise is therefore at least $58.1 million ($94,500,000 - $36,400,000). That amount is the payment that Shire made to Actavis by way of the no-AG promise contained in the Reverse Payment Agreement.

84. Publicly-available information suggests that the incremental revenue that Shire paid to Actavis by the no-AG promise is even more than $58.1 million, and is at least $113 million. Shire disclosed that it received $49.8 million in Intuniv royalty revenue from Actavis,[6] which suggests that Actavis earned $199.2 million in gross profits from sales of generic Intuniv during the first 6 months since the Agreement required Actavis to pay Shire royalty income of 25% of gross profits on Actavis's sales of generic Intuniv during the first 6 months that the no-AG promise was in effect (and .25 * $199,200,000 = $49,800,000). Assuming Actavis earned at least $199.2 million in sales revenues during the first 6 months that the no-AG promise was in effect, less the $49.8 million in royalty payments to Shire pursuant to the agreement, then Actavis earned sales revenues of at least $149.4 million during the first 6 months that the no-AG promise was in

[6] *See* Shire PLC, form 10-K for the fiscal year ended December 31, 2014, at p. 56 (reporting $22.0 million in Intuniv royalty income from Actavis in 2014); Shire PLC, form 10-K for the fiscal year ended December 31, 2015, at p. 60 (reporting $27.8 million in Intuniv royalty income from Actavis in 2015).

effect ($199,200,000 - $49,800,000). Using this estimate, the incremental revenue that Shire paid to Actavis by the no-AG promise is at least $113.0 million ($149,400,000 - $36,400,000), which also suggests that Shire sacrificed substantial AG revenues as a result of its no-AG promise.

85. From Shire's perspective, the Reverse Payment Agreement proved to be hugely profitable. The Agreement was executed in April 2013, and delayed generic entry until December 1, 2014 — extending Shire's monopoly period for approximately 19 months. Intuniv had annual sales of approximately $350 million at the time of the Agreement. With generic entry, Shire would have lost about 80% of its sales within 6 months and 90% of its sales within 12 months, but was able to retain those sales without generic entry. Thus, as a result of the Agreement, Shire realized approximately $463.75 million in additional branded sales ($350,000,000 * .8 for the first twelve months plus $350,000,000 * .9 * 7/12 for the next seven months).

86. Although Plaintiff does not assume the burdens of production or proof on Defendants' affirmative defenses by so doing, Plaintiff nevertheless avers that Defendants can offer no cognizable, nonpretextual justification or explanation for the reverse payment. The reverse payment is far greater than Shire's avoided litigation costs, and was not for services to be provided by Actavis to Shire. Indeed, Actavis was not required to perform any services in exchange for the unlawful payment according to the Reverse Payment Agreement. Actavis provided no value to Shire under the Agreement other than impermissible agreement to delay competition. The reverse payment was made in order to induce Actavis to stay out of the extended-release guanfacine market until December of 2014 and to allow Defendants to share monopoly profits.

87. This large, unjustified payment has no rational connection to, and far exceeds, any approximation of the costs of continuing the patent litigation. A

recent survey by the Association of Intellectual Property Lawyers of America estimated that the median total cost of patent infringement litigation associated with ANDA filings under the Hatch-Waxman Act was just $6 million.[7] The litigation costs that Shire avoided are likely significantly lower than $6 million, because at the time it settled with Actavis, the patent case had been pending for years and had already proceeded past trial.

88. The evidence amassed during and prior to the patent litigations showed that the patents purportedly covering Intuniv would not withstand scrutiny. Moreover, the millions of dollars that Shire paid to Actavis as part of the unlawful Agreement "provide a workable surrogate for [the] patent[s'] weakness[es]." *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223, 2236-37 (2013). "An unexplained reverse payment," like the payment at issue here, "itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236.

B. Anticompetitive Purpose and Effect of Defendants' Conduct

89. The unlawful Reverse Payment Agreement enabled Defendants to: (a) delay the entry of less expensive generic versions of Intuniv products in the United States for approximately 19 months; (b) delay the introduction of an authorized generic version of Intuniv for 6 additional months, which otherwise would have appeared on the market coincident with initial generic competition; (c) fix, raise, maintain or stabilize the price of extended-release guanfacine products; (d) maintain a monopoly in the U.S. market for extended-release guanfacine products; (e) allocate 100% of the United States market for extended-release guanfacine to Shire for approximately 19 months; and (f) allocate 100% of United States sales of generic extended-release guanfacine to Actavis for 6 months.

[7] American Intellectual Property Lawyers Association, *2013 Report of the Economic Survey*, at 34 (2013). This figure represents branded drugs with sales "at risk" of at least $25 million; for less valuable branded drugs, the median litigation costs were less than $6 million.

90. But for the unlawful Agreement (a) Actavis would have begun selling its generic version of Intuniv at risk in May 2013; (b) Shire would have launched an authorized generic version of Intuniv simultaneously with Actavis's earlier entry; and (c) other generic manufacturers would have come to market earlier, after the earlier elapsing of Actavis's 180-day exclusivity period.

91. The Reverse Payment Agreement created a bottleneck in the generic market for Intuniv. Had Actavis launched in May 2013, its 180-day exclusivity period would have been triggered commensurately earlier. At least four additional generic competitors were ready to enter the market, and would have done so earlier but-for the Agreement. Indeed, Teva, Sandoz, and TWi all had tentative FDA approvals in 2013 (which but for Actavis's 180-day exclusivity would have been final FDA approvals). As multiple generics entered the market, it would have caused substantial generic price erosion.

VII. INTERSTATE COMMERCE

92. At all material times, Shire manufactured, promoted, distributed, and sold substantial amounts of Intuniv (and Actavis manufactured, promoted, distributed, and sold substantial amounts of generic Intuniv) in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, including its territories, possessions and the Commonwealth of Puerto Rico.

93. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Intuniv and generic Intuniv.

94. In furtherance of their efforts to monopolize and restrain competition in the market for extended-release guanfacine, Defendants employed the United States mail and interstate and international telephone lines, as well as

means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VIII. MONOPOLY POWER AND MARKET DEFINITION

95. At all relevant times, Shire had market and/or monopoly power over extended-release guanfacine because it had the power to maintain extended-release guanfacine prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Intuniv, with the exception of AB-rated generic versions of Intuniv.

96. A small but significant, non-transitory price increase to Intuniv by Shire would not have caused a significant loss of sales to drug products other than AB-rated generic versions of Intuniv.

97. Intuniv does not exhibit significant, positive cross elasticity of demand with respect to price with any product other than AB-rated generic versions of Intuniv.

98. Because of, among other reasons, its approved indication, Intuniv is differentiated from all products other than AB-rated generic versions of Intuniv.

99. Shire needed to control only Intuniv and its AB-rated generic equivalents, and no other products, in order to maintain the price of Intuniv profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Intuniv would render Shire unable to profitably maintain its supracompetitive prices for Intuniv without losing substantial sales.

100. Shire sold Intuniv at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

101. Shire has had, and exercised, the power to exclude and restrict competition to Intuniv and its AB-rated generics.

102. Shire's reverse payment to Actavis demonstrates that Shire enjoyed market and/or monopoly power with respect to extended-release guanfacine.

103. Shire, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

104. To the extent that Plaintiff may be legally required to prove market and/or monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is extended-release guanfacine (*i.e.*, Intuniv and its AB-rated generic equivalents). During the period relevant to this case, Shire was able to profitably maintain the price of extended-release guanfacine well above competitive levels.

105. The relevant geographic market is the United States, including its territories, possessions and the Commonwealth of Puerto Rico.

106. At all relevant times, Shire's market share in the relevant market was 100%, implying a substantial amount of market power.

IX. EFFECTS ON COMPETITION AND DAMAGES

107. Actavis's ANDA was approved October 5, 2012. Were it not for the unlawful reverse payment and Reverse Payment Agreement alleged herein, Actavis would have entered the market at risk in or around May 2013. One or more other generic Intuniv products would have entered the market six months thereafter, and certainly sooner than they actually did.

108. But for the unlawful Reverse Payment Agreement, an authorized generic version of Intuniv would have been available on the market simultaneously with the launch of Actavis's generic.

109. Defendants' unlawful Reverse Payment Agreement, which delayed introduction of generic versions of Intuniv in the United States, has caused Plaintiff and the Class to pay more than they would have paid for extended-release guanfacine.

110. Typically, generic versions of brand drugs are initially priced

significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of brand drugs are rapidly substituted with generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand drug continues to lose even more sales to the generics.

111. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

112. But for Defendants' unlawful Agreement, direct purchasers, such as Plaintiff and members of the Class, would have paid less for extended-release guanfacine by (a) substituting purchases of less-expensive AB-rated generic Intuniv for their purchases of more-expensive brand Intuniv, (b) paying less for their remaining brand Intuniv purchases, and/or (c) purchasing generic Intuniv at lower prices sooner.

113. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to protect.

114. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Intuniv directly from Shire and purchased substantial amounts of generic Intuniv directly from Actavis. As a result of Defendants' illegal conduct as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their extended-release guanfacine requirements. Plaintiff and the other Class members paid prices for extended-release guanfacine that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because:

(1) Class members were deprived of the opportunity to purchase lower-priced generic Intuniv instead of more expensive brand Intuniv; and (2) Class members paid artificially inflated prices for extended-release guanfacine.

115. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 1 (AGREEMENT UNREASONABLY RESTRAINING TRADE)

116. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

117. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

118. In or about April 2013 and at times prior to the formal execution thereof Defendants entered into the Reverse Payment Agreement, an illegal contract, combination and conspiracy in restraint of trade under which Shire agreed to make a large reverse payment to Actavis in exchange for Actavis's agreement to delay bringing its generic version of Intuniv to the market for up to 19 months, the purpose and effect of which was to: (a) allocate 100% of the market for extended-release guanfacine in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Shire; (b) delay the availability of generic versions of Intuniv in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, thereby protecting Intuniv from any generic competition; (c) delay the entry of Shire's authorized generic until 6 months after Actavis's entry with a generic Intuniv product, and allocate 100% of sales for generic Intuniv in the United States, including its territories, possessions and the

Commonwealth of Puerto Rico, to Actavis prior to that time; and (d) fix, at supracompetitive levels, the price at which direct purchasers would pay for extended-release guanfacine.

119. The Agreement harmed Plaintiff and the Class as set forth above.

120. Defendants are liable for the Agreement under a rule of reason standard.

121. There is and was no legitimate, non-pretextual, procompetitive justification for the payment from Shire to Actavis that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

122. As a direct and proximate result of Defendants' agreement in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid.

CLAIM II: VIOLATION OF 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE)

123. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

124. At all relevant times, Shire possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Shire possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

125. Through the Reverse Payment Agreement, Shire and Actavis conspired to maintain Shire's monopoly power in the relevant market in order to block and delay market entry of generic Intuniv.

126. The Reverse Payment Agreement (a) allocated 100% of the market for extended-release guanfacine in the United States, including its territories,

possessions and the Commonwealth of Puerto Rico, to Shire; (b) delayed the availability of generic versions of Intuniv in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, thereby protecting Intuniv from any generic competition; (c) delayed the entry of Shire's authorized generic until 6 months after Actavis's entry with a generic Intuniv product, and allocated 100% of sales for generic Intuniv in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Actavis prior to that time; and (d) fixed, at supracompetitive levels, the price at which direct purchasers would pay for extended-release guanfacine.

127. The goal, purpose and/or effect of the Agreement was to maintain and extend Shire's monopoly power in the United States market, including its territories, possessions and the Commonwealth of Puerto Rico, in the market for extended-release guanfacine, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Agreement was intended to and did prevent and/or delay generic competition to Intuniv and enabled Shire to continue charging supracompetitive prices for Intuniv without a substantial loss of sales.

128. Defendants knowingly and intentionally conspired to maintain and enhance Shire's monopoly power in the relevant market.

129. Defendants specifically intended that their Agreement would maintain Shire's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

130. Defendants each committed at least one overt act in furtherance of the conspiracy.

131. As a direct and proximate result of Defendants' concerted monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

CLAIM III: VIOLATION OF 15 U.S.C. § 2 (MONOPOLIZATION)

132. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

133. This claim is pled as to Shire only.

134. At all relevant times, Shire possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Shire possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

135. Through the anticompetitive conduct, as alleged extensively above, Shire willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

136. It was Shire's conscious object to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

137. Shire's anticompetitive conduct harmed competition as alleged herein.

138. As a direct and proximate result of Shire's illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed as alleged herein.

CLAIM IV: VIOLATION OF 15 U.S.C. § 2 (ATTEMPTED MONOPOLIZATION)

139. Plaintiff hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

140. This claim is pled as to Shire only.

141. Through the Reverse Payment Agreement, Shire specifically intended to maintain monopoly power in the relevant market. It was Shire's

conscious objective to control prices and/or to exclude competition in the relevant market.

142. The natural and probable consequence of Shire's anticompetitive conduct, which was intended by Shire, and plainly foreseeable to Shire, was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

143. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Shire would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

144. As a direct and proximate result of Shire's illegal and monopolistic conduct, Plaintiff and the Class were harmed as alleged herein.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of themselves and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

XII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demand a trial by jury on all issues so triable.

Dated: January 11, 2017

HAGENS BERMAN SOBOL SHAPIRO LLP

By: **/s/ Thomas M. Sobol**

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